4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0480]

Integrated Food Safety System Online Collaboration Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of the National Center for Food Protection and Defense (NCFPD). The goal of the NCFPD is to provide well-established and high-level access to Food/Agriculture Sector Organizations and coordination of electronic collaborative tools; collaborative support from the Department of Health and Human Services (HHS), the Department of Homeland Security (DHS), and the U.S. Department of Agriculture (USDA). NCFPD also has past experience directly supporting the President's Food Safety Working Group Objectives to integrate the food safety system at all levels.

DATES: Important dates are as follows:

- 1. The application due date is July 15, 2015.
- 2. The anticipated start date is September 2015.
- 3. The opening date is May 15, 2015.
- 4. The expiration date is July 16, 2015.

ADDRESSES: Submit electronic applications to: http://www.grants.gov. For more information, see section III of the SUPPLEMENTARY INFORMATION section of this notice. FOR FURTHER INFORMATION CONTACT: Nicola Areshenko, Food and Drug Administration, Office of Regulatory Affairs, 253-987-7921, email:

Nicola.areshenko@fda.hhs.gov; or Dan Lukash, Grants Management Specialist, Food and Drug Administration, Office of Acquisitions & Grant Services, 240-402-7596, daniel.lukash@fda.hhs.gov.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at http://grants.nih.gov/grants/guide (select the "Request for Applications" link), http://www.grants.gov (see "For Applicants" section), and http://www.grants.gov/web/grants/search-grants.html?keywords=rfa-fd-15-024. SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA-FD-15-021

93.103

A. Background

Food can become contaminated at many different points--on the farm, in processing or distribution facilities, during transit, at retail and food service establishments, and in the home. In recent years, FDA, in cooperation with other food regulatory and public health agencies, has done a great deal to prevent both intentional and unintentional contamination of food at each of these points. FDA has worked with other Federal, State, local, tribal, territorial, and foreign counterpart food safety regulatory and public health agencies, as well as with law enforcement

and intelligence-gathering agencies, and with industry, consumer groups, and academia, to strengthen the nation's food safety and food defense system across the entire distribution chain.

This cooperation has resulted in greater awareness of potential vulnerabilities, the creation of more effective prevention programs, new surveillance systems, and the ability to respond more quickly to outbreaks of foodborne illness. However, changes in consumer dietary patterns, changes in industry practices, changes in the U.S. population, an increasingly globalized food supply chain, and new pathogens and other contaminants pose challenges that are requiring us to adapt our current food protection strategies.

At the Federal level, a number of agencies are working together to coordinate their efforts and develop short- and long-term agendas to make food safer. As the Federal regulatory Agency responsible for most of the nation's food supply, FDA is committed to ensuring that the food supply is among the safest in the world. This requires a systematic, integrated approach to effective risk control and enforcement strategies. Together with our Federal, State, local, tribal, and territorial public health partners, FDA is working to plan and implement an inspection and enforcement program to ensure high rates of compliance with the Agency's food safety standards. FDA intends to establish a fully integrated national food safety system built on collaboration among all of these partners. This system will encompass inspections, laboratory testing, and outbreak response and will place priority on preventing foodborne illness, in both food for humans and animals. This collaboration will result in: (1) Better ability to assess potential risk at domestic food facilities and greater and more consistent inspectional coverage of these facilities across the entire food supply chain, (2) greater food surveillance through

¹ FDA is the Federal Agency that is responsible for regulating most of the country's food supply, with the exception of most meat, poultry, and processed egg products, which are overseen by the USDA.

² For purposes of this document, the term "food" includes human food, animal feed, components (i.e. ingredients) of both food and feed, and dietary supplements for humans, except as otherwise noted.

integration of food facility inspection and testing information, and (3) improved rapid response capacity and efficiency.

Current leveraging efforts have not been sufficient to ensure adequate oversight of the entire food supply chain. Food facilities are not uniformly inspected, data are not uniformly captured on a national basis, and the data that are collected are not systematically mined for intelligence. Neither FDA nor our regulatory or public health partners alone collect and analyze a sufficient number of surveillance samples per year to have confidence in to the ability to effectively identify potential areas of concern; combining the data from all public health partners would greatly enhance FDA's ability to detect potential problems. In addition, national response efforts are uneven. Throughout the years, numerous reports have concluded that FDA does not take full advantage of the inspectional and surveillance capabilities of our state, territorial, tribal and local regulatory and public health partners. This is due in large part to the varied standards and laws in each state as compared with the Federal system, as well as to the lack of interoperable data systems and legal impediments to sharing data among partners.

These combined factors present a challenge in managing and responding to signals of public health concern in the food supply. The currently decentralized U.S. public health and agriculture system results in a situation in which responsibility for surveillance, detection, investigation, response, and recovery to foodborne disease outbreaks is shared across Federal, State, territorial, tribal, and local government agencies.

Various levels of government are working to improve the nation's food safety and defense system. At all levels, there is a call for greater integration and coordination between the Federal agencies and the regulatory and public health partners involved in food safety. An integrated food safety system will allow FDA to meet the President's Food Safety Working

Group recommendation that the Federal government "...prioritize crucial inspection and enforcement activity across the world, support safety efforts by States, localities, and businesses at home; and utilize data to guide these efforts and evaluate their outcomes."

To be fully successful, the national food safety system must be built with continuous input from FDA's regulatory and public health partners. Efforts shall facilitate information sharing and communication among all partners, and include infrastructure for a national electronic information-sharing mechanism. These actions will result in a national food safety system that identifies sources of risk throughout the system and reduces time to detect and respond to foodborne outbreaks. A public health-driven, collaborative, and leveraged approach to food safety activities and responsibilities will be reflected in improved public sector resource utilization at a national level, which provides additional capacity for ensuring a safe and secure food supply.

B. Research Objectives

The Office of Regulatory Affairs, in coordination with FDA's Office of Foods, Center for Food Safety and Applied Nutrition, and Center for Veterinary Medicine, is soliciting a cooperative grant proposal to expedite program development to support critical federal-state collaboration necessary to plan and implement an integrated food safety system. The intent is to fund proposals for the continued development and operations of collaborative online tools involving a range of stakeholders for the purposes of: (1) Information sharing in the development of an integrated food safety system and (2) developing and implementing a sustainable model for continued collaborative communication and information sharing. This grant opportunity is limited to organizations receiving funding under the current Integrated Food Safety System Online Collaboration Development cooperative agreement. The NCFPD, a DHS

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³ President's Food Safety Working Group Key Findings Report submitted to President Obama on July 7, 2009.

Center of Excellence, has unique expertise and capacity found nowhere else. It is the host/creator of FoodSHIELD, an inter-governmental collaborative project supporting information sharing at the Federal, State, and local levels. NCFPD is uniquely qualified to provide: Well-established and high-level access to Food/Agriculture Sector Organizations and coordination of electronic collaborative tools; collaborative support from HHS, DHS, and the USDA. NCFPD also has past experience directly supporting the President's Food Safety Working Group Objectives to integrate the food safety system at all levels.

C. Eligibility Information

The following organizations/institutions are eligible to apply:

This cooperative agreement is only available to organizations receiving funding under the current Integrated Food Safety System Online Collaboration Development cooperative agreement. Competition is limited to NCFPD because it is uniquely qualified and has expertise and capacity found nowhere else. It is the host/creator of FoodSHIELD, an intergovernmental collaborative project supporting information sharing at the federal, state and local levels.

NCFPD is uniquely qualified to provide: Well-established and high-level access to Food/Agriculture Sector Organizations and coordination of electronic collaborative tools; collaborative support from HHS, DHS, and the USDA. NCFPD also has past experience directly supporting the President's Food Safety Working Group Objectives to integrate the food safety system at all levels.

II. Award Information/Funds Available

A. Award Amount

One award up to \$680,000 for fiscal year 2015 with up to an additional 4 years funding up to \$680,000 per year.

B. Length of Support

Up to 5 years.

III. Electronic Application, Registration, and Submission

Only electronic applications will be accepted. To submit an electronic application in response to this FOA, applicants should first review the full announcement located at http://grants.nih.gov/grants/guide. (FDA has verified the Web site addresses throughout this document but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.) For all electronically submitted applications, the following steps are required.

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With System for Award Management (SAM)
- Step 3: Obtain Username & Password
- Step 4: Authorized Organization Representative (AOR) Authorization
- Step 5: Track AOR Status
- Step 6: Register With Electronic Research Administration (eRA) Commons
 Steps 1 through 5, in detail, can be found at

http://www07.grants.gov/applicants/organization_registration.jsp. Step 6, in detail, can be found at https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp. After you have followed these steps, submit electronic applications to: http://www.grants.gov.

Dated: May 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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